

**REMARKS**

This Amendment is responsive to the Office Action mailed January 13, 2009. With this Amendment, claim 1 has been amended. Claims 2-3, 10, and 12 are deemed withdrawn as directed to a non-elected invention. Claims 1-4 and 6-13 are pending.

**Information Disclosure Statement**

Applicants thank the Examiner for acknowledgement of receipt of the Information Disclosure Statements filed July 17, 2008 and November 3, 2008. In addition, Applicants thank the Examiner for consideration of all the documents listed therein, as indicated by the Examiner's initials and electronic signature.

**Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

The Office Action rejects claims 1, 4, 6-9, 11, and 13 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In particular, the Office Action states that claim 1 is indefinite for recitation of "derived from the nucleotide sequence represented by SEQ ID NO: 1 by the substitution, deletion, addition, and insertion of two to five bases." In addition, the Office Action alleges that claim 13 is indefinite for not clearly indicating the relative position of specific substitutions recited in the claim.

In response, and without acquiescing to the propriety of the rejections, Applicants have amended claim 1 to be even clearer and more definite. Applicants submit that the instant amendment is responsive to the rejections of both claim 1 and claim 13. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 1, 4, 6-9, 11, and 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Action alleges that Applicants (1) do not describe any DNAs ‘derived from’ SEQ ID NO: 1 that function as an IRES, and (2) do not describe SEQ ID NO:1 as having IRES activity in any plant other than *Arabidopsis*.

In response, Applicants submit that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Furthermore, and while not acquiescing to the propriety of any of the assertions made in the rejection of the claims under 35 U.S.C. § 112 (written description), Applicants respectfully submit that the present amendment addresses the instant rejection.

In particular, Applicants submit that the specification fully describes the claimed subject matter. For example, the specification describes sixteen variants of SEQ ID NO: 1 with IRES activity in plants, including those set forth on page 6, paragraph [0025]. In addition, the specification provides examples of two different constructs, one comprising repeats of SEQ ID NO: 1 without spacer sequence in between the repeats, and one comprising repeats of SEQ ID NO: 1 with spacer sequences (specification at pages 21-22, paragraphs [0074]-[0075]). The specification describes such constructs and discloses that both are capable of functioning as an IRES in plants (*Id.* and Figure 4).

Applicants further submit that the specification describes the use of plants belonging to various families including, but not limited to *Brassicaceae* (e.g., thale-cress), *Poaceae* (e.g., maize), *Solanaceae* (e.g., tobacco), and *Leguminosae* (e.g., soybean) that are to be transformed

and used with the disclosed IRES sequences (specification at, e.g., paragraphs [0055]-[0056]). Thus, the specification provides written description support of the disclosed and claimed genus, including a sufficient number of representative species of the genus and sufficient recitation of physical, structural, chemical, and functional properties of the claimed subject matter.

Based at least on the foregoing, Applicants submit that the claimed subject matter was described in the specification in such a way as to convey to those skilled in the art that Applicants were in possession of the claimed invention at the time of filing. Therefore, Applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph.

The Office Action also rejects claims 1, 4, 6-9, 11, and 13 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Action alleges that the specification, while being enabling for a polynucleotide comprising 10 repeats of SEQ ID NO: 1 that functions as an IRES in *Arabidopsis*, and a vector comprising said polynucleotide and a transformed *Arabidopsis* plant comprising said polynucleotide, does not reasonably provide enablement for a polynucleotide comprising DNA of SEQ ID NO: 1 or a DNA ‘derived from’ SEQ ID NO: 1, or for IRES activity in any plant other than *Arabidopsis*. In particular, the Action alleges that the state of the art is such that one of skill in the art cannot predict the species of plants in which an IRES will function, and that IRES function is highly unpredictable. The Office Action also alleges that the sequences provided in the specification on page 6 (SEQ ID NOs: 5-20) have not been shown to have IRES activity.

In response, Applicants submit that the specification provides sufficient guidance such that one of skill in the art could make and use the claimed invention without undue

experimentation. Furthermore, and while not acquiescing to the propriety of any of the assertions made in the rejection of the claims under 35 U.S.C. § 112 (enablement), Applicants respectfully submit that the amendment addresses the instant rejection. Applicants have, for example, amended claim 1 to recite “[a]n isolated polynucleotide which functions as an IRES (internal ribosome entry site) in a plant and comprises seven to ten repeats of the following DNA (a) or (b):

- (a) DNA of the nucleotide sequence represented by SEQ ID NO: 1; or
- (b) DNA of the nucleotide sequence represented by SEQ ID NO: 1 having two to five base modifications chosen from base substitutions, deletions, additions, and insertions, wherein said DNA has a function of positively regulating the translation of a nucleic acid located downstream thereof.”

Applicants further submit that whether or not an Applicant’s invention is enabled has been determined by the courts to involve several factors including the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicants submit that the specification provides sufficient guidance with respect to the encompassed sequences, such that one of ordinary skill in the art could make and use the invention without undue experimentation. Applicants further assert that the skill level of one of ordinary skill in this particular art is high, and that one of ordinary skill in the art would know, based on the instant disclosure, nucleic acid sequences involved in positively regulating the translation of coding regions located downstream.

Applicants wish to emphasize that the disclosure provides the detailed sequence structure for exemplary nucleic acids encompassed by the claims. Indeed, the specification indicates particular nucleotides, which can be modified and still retain IRES function (see SEQ ID NOs: 5-20, and paragraph [0024] on page 6). Applicants remind the Office that MPEP 2164.04 states that the examiner, not the applicant, has the “initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” Applicants further submit that “[a] specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” MPEP 2164.04.

Applicants also submit that the claimed invention is also enabled for at least the reasons set forth in Applicants’ response to the rejection of the claims under 35 U.S.C. § 112, first paragraph (written description), e.g., the specification describes (1) along with SEQ ID NO: 1, sixteen variants with IRES activity in plants, including those set forth on page 6, paragraph [0025]; and (2) plants belonging to various families including, but not limited to *Brassicaceae* (e.g., thale-cress), *Poaceae* (e.g., maize), *Solanaceae* (e.g., tobacco), and *Leguminosae* (e.g., soybean) that are to be transformed and used with the disclosed IRES sequences.

Based on at least the foregoing, Applicants submit that the instant disclosure provides clear and sufficient guidance such that the claimed invention is enabled. Applicants respectfully

request reconsideration and withdrawal of the rejections under the enablement requirement of 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 U.S.C. §102(b)

The Office Action rejects claims 1, 4-6, 8, 9, and 13 under 35 U.S.C. § 102(b) as allegedly anticipated by Alonso et al. (GenBank Accession No. BH789726 (2002); hereinafter “ALONSO”).

The Office Action also rejects claims 1, 4-9, 11, and 13 under 35 U.S.C. §§ 102(a) and 102(e) as being anticipated by La Rosa (U.S. Patent Application Publication No. 2004/0031072; hereinafter “LA ROSA”).

The Office Action also rejects claims 1, 4-8, 11, and 13 under 35 U.S.C. § 102(b) as being anticipated by Akbergenov et al. (*Nucleic Acids Research* 32:239-247, 2004; hereinafter “AKBERGENOV”).

In response, Applicants submit that the claims as amended are not anticipated by ALONSO, LA ROSA, or AKBERGENOV. In particular, Applicants submit that neither ALONSO, LA ROSA nor AKBERGENOV disclose “[a]n isolated polynucleotide which functions as an IRES (internal ribosome entry site) in a plant and comprises seven to ten repeats of the following DNA (a) or (b):

(a) DNA of the nucleotide sequence represented by SEQ ID NO: 1; or

(b) DNA of the nucleotide sequence represented by SEQ ID NO: 1 having two to five base modifications chosen from base substitutions, deletions, additions, and insertions, wherein said DNA has a function of positively regulating the translation of a nucleic acid located downstream thereof."

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(a), (e), and (b).

**CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

No additional fee is believed due at this time. If, however, any additional fee is necessary to ensure consideration of the submitted materials, the Patent and Trademark Office is hereby authorized to charge the same to Deposit Account No. 19-0089.

Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully Submitted,  
Minami MATSUI et al.

  
Bruce H. Bernstein  
Reg. No. 29,027 *42,920*

April 13, 2009  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191